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TITLE: Development of a PTSD Population Registry

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14. ABSTRACT

The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with posttraumatic stress disorder (PTSD). This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to evaluate risk factors for PTSD among combat-exposed service men and women. Since September of 2010, data were collected on 265 men and 324 women. Of these participants, 75% met criteria for PTSD. To date, 765 phase 2 participants have completed.

15. SUBJECT TERMS
Risk factors for PTSD. PTSD symptom development and VA healthcare utilization

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INTRODUCTION

The purpose of this project is to develop the first longitudinal registry of combat-exposed men and women with PTSD. This registry will provide essential data on the natural history and outcomes associated with PTSD in military service men and women who have utilized the Department of Veterans Affairs (VA) health care system. An additional goal of this project is to determine risk factors for PTSD among combat-exposed service men and women (by incorporating a combat-exposed non-PTSD group of veterans into analyses). Thus, the registry will allow an evaluation of current theoretical models of symptom development in a large sample of service men and women who utilize the VA medical system.

BODY

Research technicians attempted to make contact with the remaining potential participants from the level 1 roster. After 2 opt out letters were sent to all 3,000 participants from the level 1 roster, 1,232 non-responders from the roster remained. Research technicians then contacted all remaining non-responders by phone, as outlined in the project protocol. In month 25 of the project, a new level 1 roster of 6,000 potential participants was received. In months 25 through 34 initial opt out letters were sent to all 6,000 participants on the roster. Of the 6,000 letters mailed, 1,959 were returned. Currently, a second round of opt-out letters is being sent to the 4,041 participants who did not respond to the initial mailing. Of the 6000 participants who have been contacted, 1,372 returned letters agreeing to be contacted about the study, and 222 returned letters declining to be contacted further. Five hundred and fifty-eight (558) recruitment letters have been returned for bad addresses. A second opt-out letter was sent to these participants using the secondary address that was provided with the second level 1 roster. At present, 765 phase 2 participants have completed the project.

To date, no problems have impeded performance of the project.

Personnel receiving salary from this research effort are Darren Holowka, Ph.D. (project coordinator and clinical interviewer), Katharine Glossner (research technician), Heather Fink (research technician) and Monica Durham (clinical interviewer).

KEY RESEARCH ACCOMPLISHMENTS

- Phase 2 recruitment is ongoing

REPORTABLE OUTCOMES

- Gates, M.A., Holowka, D. W., Vasterling, J.J., Keane, T.K., Marx, B.P. & Rosen, R. C. (Under Review). Posttraumatic Stress Disorder in veterans and Military Personnel: Epidemiology, Screening & Case Recognition. *Psychological Services*.

- Holowka, D.W., Marx, B.P., Rodriguez, P., Gates, M, Rosen, R.C. & Keane, T.M. (2011, March). Medical Chart PTSD Diagnostic Accuracy among OEF/OIF Veterans: Preliminary Results. Poster presented at the 31st annual meeting of the Anxiety Disorders Association of America, New Orleans, LA.

- Holowka, D.W., Marx, B.P., Gates, M.A., Guey, L. Rosen, R.C., Vasterling, J.J. & Keane, T.M. (2011, November). Posttraumatic Stress Disorder, Mild Traumatic Brain Injury, & Psychosocial Functioning among Iraq and Afghanistan Veterans. Poster to be presented at the annual meeting of the International Society for Traumatic Stress Studies, Baltimore, MD.

- Gates, M.A., Holowka, D.W., Rodriguez, P., Keane, T.M., Marx, B.P., Rosen RC. (2011, June) A longitudinal registry of post-traumatic stress disorder in OEF/OIF veterans: The early recruitment experience. Poster presented at the 3rd North American Congress of Epidemiology. Montreal, Canada.

- Miller, M.W., Wolf, E., Marx, B., Holowka, D., Resnick, H., Kilpatrick, D., Gates, M., Rosen, R., Guey, L., Keane, T., Friedman, M. (2011, November). Pilot Study of a DSM-V internet survey instrument in a U.S. Department of Veterans Affairs PTSD sample. Paper to be presented as part of a symposium titled *Internet Surveys on Proposed DSM-5 Criteria for PTSD* (M. Friedman, chair) at the 27th annual meeting of the International Society for Traumatic Stress Studies, Baltimore, MD.

CONCLUSION

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand the etiology and course of PTSD, how it can be identified at early stages, and the responsiveness of recent returnees to various treatment options. This knowledge will be of benefit to policy makers and current service members as well as victims of trauma in the broader community. It will include:

- Evaluation of the natural history and long-term outcomes of PTSD across treatments, treatment settings, and practitioners, using cost-efficient methods and economies of scale;
- A more accurate assessment of current theoretical models of symptom development, and
- Documentation of health resource utilization and development of a database that is an ideal resource for health services planning and policy.

Furthermore, this study will contribute:

- The formation of a potential cohort of subjects for ancillary studies, ranging from genomic influences to quality of life and psychosocial outcomes, as well as future clinical trials;
- The creation of a representative sample of PTSD OEF/OIF Veterans who use the VA medical system, available for use in epidemiologic studies, particularly for comparisons with active duty and other Veteran or civilian populations;
- Utility to clinicians, patient advocacy groups, and health policy planners;
- Publications and dissemination of the registry results to provide a representative perspective of what is achieved in actual current care settings, thereby augmenting outcomes data from clinical trials.

APPENDIX
AMENDED STATEMENT OF WORK – MAY 12, 2011

12-MONTH NO-COST EXTENSION START DATE- September 1, 2011

VA Boston Healthcare System (BVARI)
Institutes, Inc. (NERI)
Research Service (151)
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New England Research

9 Galen Street
Watertown MA 02472
Partnering PI: Raymond

This project requires human subject participation.

Major Task (Milestone)	Timeline (Months)	BVARI	NERI
PHASE I – STUDY INITIATION			
IRB Approvals/Finalize Protocol			
Finalize Protocol; NERI/VHA IRB approvals and USAMRMC HRPO human subject protocol approval	Completed	TK/BM	RR
Program and Test De-Identification			
Programs to de-identify VA in/outpatient electronic records database will be created	33-36	TK/BM	RR
De-identification programs will be tested on sample data	33-36	TK/BM	RR
Design statistical analysis programs	33-45	TK/BM	RR
PHASE II – DATA COLLECTION			
Prepare Data for Abstraction			
Data on potential participants will be merged from electronic databases	Completed	TK/BM	
Data will be de-identified	Completed	TK/BM	
Transfer data to NERI	33-45	TK/BM	RR
Resolve Queries			
Generate query reports that relate to the quality of the database based on pre-determined values	33-45		RR
Data cleaning and tracking	33-45		RR
Pretest telephone Interview Instrument			
The interview will be tested in a sample of 20 veterans who will not be enrolled in the study to assess burden, ease of comprehension and time to completion	Completed	TK/BM	
Make modifications based on pre-testing	Completed	TK/BM	RR
Final interview tested to allow completion in a 40-50 minute telephone call	Completed	TK/BM	
Develop manual of operations	Completed	TK/BM	RR

Identify Target Sample for Interview			
Identify 1,200 OIF/OEF veterans with diagnosis of PTSD and 400 OIF/OEF veterans without diagnosis of PTSD and one or more visits during post-deployment years in the VA medical records database	Completed	TK/BM	
Conduct Interim Analyses			
Conduct interim analyses using existing PTSD Registry data	33-39		RR
Conduct Interviews			
Interviewers will be extensively trained and monitored for quality assurance	10-45	TK/BM	RR
Patients will be contacted by telephone and informed consent will be obtained verbally	21-45	TK/BM	
Patients provide verbal consent and interviews are scheduled	21-45	TK/BM	
Interview Data Entry De-Identification and Transfer			
Data entry and quality control measures will be ongoing at the VA	21-45	TK/BM	
Data will be de-identified	33-45	TK/BM	
Data will be transferred to NERI	33-45		RR
PHASE III – DATA ANALYSIS & REPORTS			
Conduct Data Analysis			
Analyses will be conducted to address the Specific Aims of the Registry	36-48		RR
Reports and Publication	36-48	TK/BM	RR
Continued Abstraction of Medical Records			
Perform abstraction periodically of VA in/outpatient electronic medical records for PTSD registrants who have return in/outpatient visits to VA medical centers	24-48	TK/BM	RR
Prepare PTSD Database for Future Use			
PTSD Registry database of 1,200 OIF/OEF veterans will be prepared for potential sharing as a public dataset	46-48	TK/BM	RR